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Date

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Alan J. Schroit

Application No.: 09/974,753

Filed: October 9, 2001

For: METHODS AND COMPOSITIONS FOR INDUCING AUTOIMMUNITY IN THE TREATMENT OF CANCERS

Group Art Unit: 1642

Examiner: G. Nickol

Atty. Dkt. No.: UTSC:594USD1/MBW

DECLARATION OF ALAN J. SCHROIT UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Alan J. Schroit, declare that:

1. I am a citizen of the United States residing at 4619 Willow St., Bellaire, Texas 77401. I am a professor of Cancer Biology at The University of Texas, MD Anderson Cancer Center ("MD Anderson").

2. I have been employed by MD Anderson for 20 years. I have extensive experience in the field of cancer biology and, more specifically, phospholipid structures and generating antitumor

responses against tumor-expressed lipid targets through specific anti-lipid autoimmune responses. Attached as Exhibit 1 is my *curriculum vitae*.

3. In providing this declaration, I have reviewed the Office Action mailed on March 20, 2003. I am also familiar with the content of the above-captioned application, as well as with the pending claims.

4. In this Office Action, the Examiner makes reference to a publication by Bate *et al.* (1993), to dispute the patentability of claims 28-31. The Bate *et al.* reference discloses a method of making a phospholipid/polypeptide conjugate by admixing phosphatidylserine and keyhole limpet haemocyanin ("KLH") with carbodiimide. See Exhibit 2 (the Bate *et al.* reference), page 139, column 2. For the reasons set forth below, it is my opinion that the resulting phospholipid/polypeptide conjugate is not a phosphatidylserine/polypeptide conjugate. It is also my opinion that the antibodies in the antisera produced by the collaborators of the Bate *et al.* reference are not phosphatidylserine specific antibodies.

5. Phosphatidylserine is a phospholipid that has a free amine group located at the phosphate head portion of the phospholipid. It is this free amine group that distinguishes phosphatidylserine from other known phospholipids, such as phosphatidylcholine.

6. To produce the phospholipid/KLH conjugate, the collaborators in Bate *et al.* coupled phosphatidylserine to KLH by mixing KLH and phosphatidylserine in the presence of carbodiimide. See Exhibit 2, page 139, column 2. This procedure couples KLH to the phosphate

head portion of phosphatidylserine *through* the free amine group on phosphatidylserine. Because of this, the phosphatidylserine used in Bate *et al.* no longer has its distinguishing feature, the free amine group.

7. Therefore, the coupling of KLH with phosphatidylserine *via* carbodiimide does not actually produce a phosphatidylerserine/KLH conjugate that preserves the phospholipids distinguishing features. It follows, then, that the antibodies produced against the conjugated product in Bate *et al.* are not specific towards phosphatidylserine.

8. I hereby declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the referenced patent application or any patent issued thereon.

6/19/03
Date

Alan J. Schroit, PhD

June 2003

EXHIBIT 1

CURRICULUM VITAE

NAME ALAN J. SCHROIT, Ph.D.

EDUCATION

1970 B.Sc., Microbiology and Biochemistry, Bar-Ilan University, Ramat-Gan, Israel.
1973 M.Sc., Microbiology, Hebrew University-Hadassah Medical School, Jerusalem, Israel.
1978 Ph.D., Immunology, Hebrew University-Hadassah Medical School, Jerusalem, Israel.

BACKGROUND

1996 - Adjunct Professor, Cardiovascular Research Institute, University of Limburg, Maastricht, The Netherlands.

1991 - Deputy Chairman, Department of Cell Biology, The University of Texas M.D. Anderson Cancer Center, Houston, Texas

1990 - Professor and Biologist, The University of Texas M.D. Anderson Cancer Center, Department of Cell Biology, Houston, Texas.

1990 - Professor of Cell Biology, Graduate School of Biomedical Sciences, The University of Texas Health Science Center at Houston.

1985 - 1990 Associate Professor and Associate Biologist, The University of Texas M. D. Anderson Cancer Center, Department of Cell Biology, Houston, Texas.

1985 - 1990 Associate Professor of Cell Biology, Graduate School of Biomedical Sciences, The University of Texas Health Science Center at Houston.

1983 - 1985 Assistant Professor of Cell Biology, Graduate School of Biomedical Sciences, University of Texas Health Science Center at Houston.

1983 - 1985 Assistant Professor and Assistant Biologist, The University of Texas System Cancer Center, M.D. Anderson Hospital and Tumor Institute, Department of Cell Biology, Houston, Texas.

1980 - 1983 Scientist, Cancer Metastasis and Treatment Laboratory, NCI, Frederick Cancer Research Facility, Frederick, Maryland.

1977 – 1980 Postdoctoral Fellow, Carnegie Institution of Washington, Department of Embryology, Baltimore, Maryland.

1971 – 1977 Research Assistant, Institute of Microbiology, Hebrew University-Hadassah Medical School, Jerusalem, Israel.

PROFESSIONAL SOCIETY MEMBERSHIPS
American Chemical Society
American Association for the Advancement of Science

PATENTS
U.S. Patent No. 4,571,332 "^{125}I-labeled Phospholipids" assigned to U.S. Government.

U.S. Patent No. 4,983,397, "Pharmaceutical Compositions Consisting of Acylated Phospholipids" assigned to Board of Regents, University of Texas System, Houston, Texas.

U.S. Patent No. 6,300,308 "Methods and Compositions for Inducing Autoimmunity in the Treatment of Cancer"

GRANT SUPPORT (Alan J. Schroit, P.I.)

NIH/NCI CA-40149 1985-1988 (approved direct costs $168,806) Liposome Activated Macrophages for the Therapy of Metastasis.

NATO 0746/88 1989-1993 (approved direct costs 500,000 B.F.) Regulation of Transmembrane Phospholipid Distribution in Human Erythrocytes and Platelets.

NIH/NCI CA-47845 1989-1994 (approved direct costs $741,498) Role of Phosphatidylserine in Pathology and Macrophage Recognition.

NIH/NCI DK-41714 1989-1994 (approved direct costs $661,206) Maintenance of Lipid Asymmetry in the Human Erythrocyte.

NIH/NCI DK-41714 1995-2000 (approved direct costs $790, 585) Maintenance of Lipid Asymmetry in the Human Erythrocyte

Texas Higher Education Board/Advanced Technology Program 1998-1999 (approved direct costs $177,000) Induction of autoreactive lipid antibody for the recognition and destruction of metastatic tumor cells.

Elsa U. Pardee Foundation. 2001 – 2003 ($120,000 direct costs) Antiphospholipid antibodies for cancer therapy.

NIH GM-64610 2002 - 2006 (direct costs $660,000) Lipid peroxidation and apoptotic cell recognition.

PUBLICATIONS
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2. Schroit, A.J., B. Geiger and R. Gallily. 1973. The capacity of macrophage components to inhibit antimacrophage serum activity. Eur. J. Immunol. 3, 354-359.

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macrophage antigenic components. In Mononuclear Phagocytes in Immunity, Infection and Pathology. (R. Van Furth, eds.) Blackwell Scientific Publications, Oxford. Pp. 363-367.

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